IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Michael YEADON, et al.	Examiner: Yong Soo Chong
Serial No.: 10/720,050	Group Art Unit: 1617
Filed: November 19, 2003	Confirmation No.: 3489

Title: COMBINATION OF A DOPAMINE D2-RECEPTOR AGONIST AND TIOTROPIUM OR A DERIVATIVE THEREOF FOR TREATING OBSTRUCTIVE AIRWAYS AND OTHER INFLAMMATORY DISEASES

RESPONSE TO SECOND RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed October 29, 2007, applicants have the following election pursuant to the addition made to the restriction requirement.

Applicants initially note that they took no action which would warrant the further restriction made in the new Office action. Applicants, thus, traverse the new restriction requirement on the grounds that a restriction has already been made and applicants provided their election. No basis has been provided to change the restriction requirement after applicants have already elected.

Applicants hereby confirm their previous election (which the Office action appears to assume) of previous Group I-A, the compositions comprising a dopamine D2-receptor agonist and an anti-cholinergic according to formula (1.1.1), with traverse. The new Office action does not address applicants' traversal, thus, it is repeated below.

As for the further restriction among every single different specifically mentioned dopamine D2-receptor agonist, applicants hereby elect Group I-Q, pramipexole, with additional traversal.

As to the new added grounds of restriction, applicants traverse on the basis that the

Groups for election set out in the Office Action do not encompass the full scope of the claims. The Groups I-A. to I-AA. only relate to embodiments where dopamine D2-receptor agonist is certain specific compounds. However, the invention is not so restricted and the Groups for election do not encompass other embodiments using other dopamine D2-receptor agonists. Thus, the restriction is traversed for failure to consider the full claimed invention.

The new restriction is further traversed because sufficient basis has not been provided for restricting between Groups I-A. to I-AA.. The Office action alleges that Groups I-A. to I-AA. are unrelated. Applicants strongly disagree. Such allegation is completely contrary to applicants' disclosure, even applicants' claims, and the knowledge of one of ordinary skill in the art. As the disclosure and claims make clear, all of the compounds A. to AA. are dopamine D2-receptor agonists. They are clearly not "totally different compounds," as alleged in the Office action. Further, there is no basis to assert that they different modes of operation, different effects and different function. To the contrary, they are all used in the invention for the same mode of operation, effect and function, i.e., to provide dopamine D2-receptor agonist activity. Further, applicants disagree that a proper search will not lead to information on each member of the group. The proper search should look for dopamine D2-receptor agonists, which will include all of the compounds.

Applicants further traverse the restriction on the grounds that there is no undue burden of search to include all the dopamine D2-receptor agonists. To the contrary, the PTO is placing an extremely undue burden upon applicants by making this restriction requirement. Coupled with the initial restriction, the current restriction requirement restricts this invention into 200 Groups (i.e., the initial four groups I-IV, times the 23 different initially restricted groups of dopamine D2-receptor agonists plus the 27 new different specific dopamine D2-receptor agonists). Thus, the PTO would like applicants to file 200 different applications (**at a cost of over $200,000**, just for the filing costs) to cover their single unitary invention here. The invention is directed to the unitary invention of the combination of the specific tiotropium anticholinergic with a dopamine D2-receptor agonist and specific methods for using such combination. Such a reasonable targeted invention does not warrant the extreme 200-way restriction imposed here.

Applicants further repeat below their initial grounds of traversal, which are not addressed in the new Office action and request full consideration thereof.

The restricted Groups for election set out in the initial Office Action do not encompass the full scope of the claims. The Groups I-IV only relate to embodiments where the tiotropium anti-cholinergic is of the configuration of formula (1.1.1), however, the invention is not so restricted and the Groups for election do not encompass other embodiments using other anti-cholinergics; see, e.g., claims 6-10. Thus, the restriction is traversed for failure to consider the full claimed invention. Applicants submit that there is no basis to restrict among the separate configuration formulas to tiotropium.

Additionally, applicants respectfully traverse the restriction among Groups IA-IW. The Office Action provides no basis whatsoever for restricting the single invention of the claimed compositions recited in claim 1 into 24 separate groups. No basis was even alleged in the initial Office action – nor in the current Office action – to support restriction among the Groups A-W. Thus, the restriction among these Groups must be withdrawn.

In any event, restriction among Groups A-W (and new Groups A. to AA.) is not supportable. Claim 1 is a proper Markush group. A Markush claim **can** contain independent and distinct inventions such that a prior art reference anticipating the claim with respect to one member would not render the claim obvious with respect to another member. The PTO's own rules on this matter set forth in M.P.E.P. §803.02 specifically state that:

> "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s)."

This section of the M.P.E.P. makes clear that such a claim is a proper Markush claim and should be examined in accordance with Markush practice. The embodiments encompassed by Groups A-W (and new Groups A. to AA.) are all dopamine D2-receptor agonists, as claim 1 makes clear. Furthermore, M.P.E.P. §2173.05(h) discusses types of improper Markush claims and applicants' claims are not of the type indicated to be improper therein. Accordingly, it is respectfully submitted that the instant claims are proper Markush claims and, therefore, restriction is not proper.

Applicants also traverse the restriction of Groups II-IV from Group I. Groups II-IV are directed to the method of use of the compositions of Group I. As the basis for restriction, the initial Office Action alleged that "another method of treating obstructive airway disease,

such as asthma, is environmental management to avoid asthma triggers and an established drug regimen including bronchodilators." However, such allegation does not support restriction among composition and method of use claims. The fact that the condition can be treated by a different method does not meet one of the requirements for supporting restriction, i.e., (1) the process can be practiced with a materially different product, or (2) the product can be used in a materially different process. As for (1), using a different product would not result in the claimed method because there is no evidence to support that a different product would provide the materially same effect. As for (2), there is no evidence to suggest the product can be used in a materially different process. The processes of Groups II-IV are within the same genus, i.e., treatment of obstructive airway other inflammatory diseases. Claim 12 is generic to each of the alleged Groups II-IV, which is why claims 13-19 are all ultimately dependent on claim 12. No proof or objective evidence is provided to support that the Groups II-IV are directed to materially different processes.

Further, it is not correct that the inventions of Group II-IV are "unrelated." Clearly they are related since each is within the genus of methods for treatment of obstructive airway other inflammatory diseases. A cursory review of the prior art in the field evidences the close relation between methods of treating asthma and COPD.

Accordingly, it is urged that the restriction of Groups II-IV from Group I and from each other is not supported on the record and should be withdrawn.

For all of the above reasons, it is urged that the restriction requirement should be withdrawn, in total.

Favorable action is earnestly solicited.

No fee is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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